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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,486	12/29/2003	Euljoon Park	A03P1088	8738

36802 7590 10/05/2005

PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
FAULCON JR, LENWOOD	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

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Office Action Summary	Application No.	Applicant(s)	
	10/748,486	PARK ET AL.	
	Examiner	**Art Unit**	
	Lenwood Faulcon, Jr.	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/23/2004*.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Alt (U.S. Patent No. 4,846,195).

Alt teaches of an implantable position and motion sensor (col. 2 lines 47-55), for use with in an implantable cardiac device (col. 2 lines 23-28). Alt also teaches of the cardiac device comprising a pulse generator, evaluation circuit, memory and a logic circuit (col. 6 lines 34-36). Alt further teaches of the cardiac device working to promote intrinsic rhythm when a patient transitions from a comparatively less upright posture to a comparatively more upright posture (col. 6 lines 61-68 and col. 7 lines 1-15). Alt teaches of the cardiac device being able to ascertain whether the patient is in a condition of rest or non-rest (col. 2 lines 55-62) and from a supine position to an upright position (col. 2 lines 38-44).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 4-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt (U.S. Patent No. 4,846,195) as applied to claims 1-3 above, in view of Pitts Crick et al. (U.S. Patent No. 6,104,949).

Pitts Crick et al. teaches of an implantable pulse generator system, that is useful in the diagnosis and treatment of congestive heart failure, by sensing the trans-thoracic impedance and patient posture (col. 1 lines 49-52). Pitts Crick et al. also teaches of a programmer that communicates with a programmer interface block, to obtain data which is transferred to storage, for use in analyzing system conditions, patient information and changing the pacing the conditions if warranted (col. 4 lines 13-19). This is interpreted by the Examiner as the ability to enable or disable an increase to the pacing response if the patient's heart is in intrinsic rhythm, after analysis of the systems condition and patient information. Pitts Crick et al. further teaches of the use of 2 and 3 axis accelerometers for measuring patient posture (col. 4 lines 9-12). Pitts Crick et al. also teaches of the ability to a respiratory related signal (col. 5 lines 37-43).

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Alt with the teachings of Pitts Crick et al. Alt and Pitts Crick et al. both teach of implantable cardiac devices that have the ability to monitor a patient's posture and adjust the pacing rate of the cardiac device accordingly, and thus teach of analogous arts. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device as taught by Alt to include

the ability to enable and disenable an increased pacing response to a sensed condition indicative of orthostatic hypotension based on an analysis of both the system's condition and the patient's information, as taught by Pitts Crick et al, since that would increase the device's effectiveness and enhance energy conservation when disenabled. It would have also been obvious to one having ordinary skill in the art at the time of the invention to modify the device as taught by Alt to also include a respiration sensor in addition to an activity sensor and accelerometer in order to provide a more accurate indication of the patient's cardiac need, as taught by Pitts Crick et al.

It would have also been obvious to one having ordinary skill in the art to modify the devices as taught by Alt and Pitts Crick et al. by having a duration of disabling increased pacing for a programmed duration of various time to provide efficient use of the battery while providing safety to the patient, as deemed necessary by a physician, since this is commonly known in the art. Further, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the devices as taught by Alt and Pitts and Crick et al. to have accelerometers of one, two and/or three axes, since accelerometers of theses axes are commonly known in the art for providing accurate measurements.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Alt and Pitts Crick et al. to have the limitations of claims 4-35.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of Park et al. (U.S. Patent No. 6,351,672) in view of Pitts Crick et al. (U.S. Patent No. 6,104,949) as discussed above.

The limitations of claim 1 of the application appear to be obvious variations of claim 1 of Park et al. A difference between claim 1 of the application and claim 1 of the patent is that the application's claim provides for promoting intrinsic rhythm when a patient transitions from a comparatively less upright posture to a comparatively more upright posture. However, one having ordinary skill in the art at the time of the invention would know that a patient's orthostatic need could be comprise the assessment of a patient's transition from a comparatively less upright posture to a comparatively more upright posture.

Likewise, claims 2-35 of the application represent similar obvious modifications one of ordinary skill in the art would make based on patented claims 1-30 of Park et al. in view of Pitts Crick et al.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sheldon (U.S. Patent No. 5,725,562), Sheldon (U.S. Patent No. 5,957,957), Sheldon et al. (U.S. Patent No. 6,044,297), Dauer et al. (U.S. Patent No. 6,134,471), Meyer (U.S. Patent No. 6,308,098), Pianca et al. (U.S. Patent No. 6,466,821), Townsend et al. (U.S. 2002/0170193), Scheiner et al. (U.S. 2002/0147475), Daum (U.S. 2002/0147476).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lenwood Faulcon, Jr. whose telephone number is 571-272-6090. The examiner can normally be reached on Monday-Thursday from 9 to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes, can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lenwood Faulcon, Jr.

George Manuel

Primary Examiner